Remarks/Arguments:

Claims 1-36 were pending in the application at the time of the Office Action. Claims 1-4, 13 and 19-21 are canceled herewith. Claim 5 is amended to incorporate matter found in claims 1, 13 and 27 as filed, and as supported in the published application at paragraph [0049]. No new matter has been added.

Claim Rejections - 35 USC § 112

1. Claims 23, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. The Examiner indicates that Applicant's wording of a molar ratio from about 5 to about 120 (and the like in the respective claims) is indefinite because "5" is not a ratio and as such it is unclear what Applicant is referring to. A molar ratio of 5:120 is held inconsistent with the claimed invention since the lactone component seems to be desired in an amount greater than that of the diol core.

Applicants amend claims 23-25 herewith to more distinctly set forth the molar ratios, and submit that the rejection has been overcome.

3. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The Examiner indicates that it is unclear what the scope of the ranges of these claims are meant to encompass, for the following reasons. There are no requirements or limitations as to what constitutes the lactone "unit" of claim 5. As per the formula of claim 5, there are 2 lactone units, each repeated at least 4 times (so 8 'units' total), 1 initiating core and 1 coupling unit. As such the lactone unit always inherently constitutes 80% (8/10 unit parts) of the polyester. The Examiner considers it unclear how one can have 10-99% of said unit in the polyester backbone.

Applicants amend claim 5 herewith to clarify the meaning of lactone "unit." Applicants also note that the Examiner's calculations are on a molar basis. Applicants amend claims 8 and 9 herewith to clarify that the percentages of the indicated units are calculated on a weight

basis, as supported in the published specification at paragraphs [0067], [0089], and [0092] through [0095]. Applicants therefore submit that the rejection has been overcome.

Claim Objections

5. Claim 5 is objected to with a statement that Applicant should keep the symbols constant throughout the claims, and that the "D" unit of the formula is inconsistent with the "C" coupling unit. The correction should be in scope with claim 15, which uses "D".

Applicants amend claim 5 accordingly, and submit that the rejection has been overcome.

6. Claims 10-12 are objected to with a statement that the lower end of the ranges therein is 50. Propiolactone, the lowest MW lactone claimed, has a MW of 72. The Examiner indicates that it is unclear how one can have a unit MW of 50.

Applicants amend claims 10-12 herewith to set the lower molecular weight limit at 288, and submit that the objection has been overcome.

7. Claim 28 is objected to with a statement that depsipeptide is not a lactone, and that therefore calling it a lactone member is improper.

Applicants respectfully disagree that depsipeptides are not lactones. Depsipeptides are lactones, as noted in paragraphs [0024] and [0053] of the published application. The latter passage clarifies that a depsipeptide is a combined lactam and lactone, as shown in the structural formula given there. For the Examiner's convenience, Applicants submit herewith a definition of "lactone" from the International Encyclopedia of Chemical Science, stating that a lactone is "one of a group of cyclic inner esters of the hydroxy acids formed by the elimination of the elements of water from one molecule of the hydroxy acid." This describes the depsipeptide structure shown at paragraph [0053]. Thus, depsipeptides are lactones and the objection should be withdrawn.

8. Claim 36 is objected to due to a misspelling of "agent" in line 1.

Claim 36 is amended appropriately herewith, and Applicants submit that the objection has been overcome.

Claim Rejections - 35 USC § 102

9. Claims 1-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Spinu (US 5202413). The Examiner argues as follows. Spinu discloses alternating ABAN polylactide block copolymers (title). The "A" block comprises lactide units derived from ring opening lactones such as those disclosed in Column 4. The "B" block is a diol having a number average MW of 500-20,000 and may be a dihydroxy ether such as polyethylene oxide and the like (Column 3 lines 25-69 and examples). The "N" [sic; Applicants believe that the Examiner meant to say "L"] coupling unit, which links ABA block copolymers together, may be diacyl chlorides having 8-20 carbon atoms, which encompasses sebacic acid, dodecanoic [sic; dodecanedioic] acid and the like, is disclosed in Column 5 line 15. Catalysts such as stannous 2-ethylhexanoate are used to react the diol with the lactone (Column 4 lines 61-62). The composition above meets the requirements of claims 1, 2, 3, 7, 13, 14, 15, 16, 19, 20, 21, 22, 26, 27, 28, 29, 30-32. Since the composition requirements of the claims are met the properties of claims 4 and 18 are found to be inherently met by the composition. Since there is no requirement in claim 5 as to how to define the lactone units, and since the MW of the blocks is at least 500, preferably at least 2000 which given a lactic acid MW of 93 means at least 5 to 20 lactic acid monomers are present, the m requirements of claims 5 and 6 are deemed met. The number of units linked by the coupling agent can be from 1 to 100 (Column 3 line 16), as further required by claim 5. Since the lactone units always inherently comprise at least 80% of the polyester (i.e. 2 A units and at least 4 repeats therein equals 8 A units, plus 1 B unit and 1 C unit, 8/10 =80%) claims 8 and 9 are met. A lactic acid "unit" would have a MW of 93, which meets the requirements of claims 10-12. The end product has a number average MW of 10,000-250,000 (Column 5 line 27), since the weight average MW is higher than the number average MW the range of claim 17 is met therein. Since the end MW and the lactone unit requirements of the claim are met it is the Examiner's position that the molar ratio is inherently met by Spinu, additionally, Ex 2 discloses a molar ratio of 71:1, Ex 3 discloses a molar ratio of 23:1, Ex 9 discloses a molar ratio of 14:1, as such the limitations of claims 23 and 24 are deemed met. The coupling agent added in a 1:1 ratio Column 5 line 17, as required by claim 25. Since there is no structural limitation of a device required in the claims the Examiner finds the end molded resins to meet the requirements of claim 33. Since there is no disclosure as to how one adapts the device in claims 34 and 35 the Examiner finds

the mere molding of an article to meet the adaptation requirement and finds the limitations of the claims met.

Applicants note that while Spinu describes polymers having some of the features of those presently claimed, none of Spinu's polymers has a [B] block as recited in present claim 5, i.e., diol residues containing C_2-C_{14} alkanediyl groups. Rather, Spinu's [B] blocks are derived from polyethers, polyesters, and silicones, generally of molecular weight from 500 to 20,000.[1] Thus, Spinu does not teach this feature, and Applicants submit that present claim 5 is therefore novel over Spinu. All of the other pending claims recite the structure of claim 5, and these should also be allowed.

10. Claims 1-14, 18-20, 22-25, 27-30 and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Fowler (US 2977385). The Examiner argues as follows. Fowler discloses lactone polymers. Said polymers are ABA type polymers (Column 1 lines 19-25) which are further chain extended with diisocyanates (Column 9 lines 19-21). The A block is derived from substituted or unsubstituted caprolactones (Column 1 lines 68-71), the B block is derived from diols such as ethylene glycol, polyethylene glycol and the like (Column 3 lines 10-15), and the composition may be further reacted with diisocyanates to form higher molecular weight products (Column 9 lines 19-24). The lactone and the diol are reacted in the presence of a catalyst such as 2-ethylhexanoic acid. The elements above meet the requirements of claims 1, 2, 3, 7, 13, 14, 19, 20, 22, 27 28, 29 and 30. Since the composition requirements are met the properties of claims 4 and 18 are deemed inherently met by the composition. The molar proportions are selected to obtain the desired MW, and a 10:1 lactone to diol ratio is disclosed in Column 10 line 75, as required by claims 23 and 24. The molar ratio of the terminating acid and the ABA polymer may be equivalent, or 1:1 (Column 10 lines 24-27), as required by claim 25, the molar ratio of 10:1 would give 10 lactone repeat units, as required by claims 5 and 6. Since the molar ratios are met it is the Examiner's position one would inherently get the "x" number of repeat units additionally required by claim 5. Since the lactone units always inherently comprise at least 80% of the polyester (i.e. 2 A units and at least 4 repeats therein equals 8 A units, plus 1 B unit and 1 C unit, 8/10 =80%) claims 8 and 9 are met. A lactic acid "unit" would have a MW of 93, which meets the requirements of claims 10-12.

[1] Spinu, column 3, lines 25-69

Applicants note that while Fowler's polymers have some of the features of those presently claimed, all of Fowler's polymers are required to have an [A] block that is made from lactones having at least six carbon atoms in the ring.[2] Indeed, Fowler explicitly teaches away from using lactones with fewer carbons.[3] In contrast, present claim 5 includes no lactone residues having six or more carbon atoms in the ring as required by Fowler, and thus, Fowler does not teach a polymer as claimed. Applicants respectfully request that the rejection be withdrawn. All of the other claims recite the structure of claim 5, and these should also be allowed.

11. Claims 1-18, 20-22 and 25-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohn (US 5711958). The Examiner argues as follows. Cohn discloses polymeric compositions comprising chain extended hydroxy-carboxylic acid/polyoxyalkylene ABA triblocks (abstract). The A block is derived from lactide, glycolic and various lactones (Column 3 lines 31-35), the B block may be polyethylene oxide and the like, and the chain extender may be diacyl halides formed from derivatizing dicarboxylic acids (Column 6 lines 43-44), wherein the dicarboxylic acids may be sebacic and the like (Column 14 lines 35- 50). The molar ratio of the chain extender to the ABA copolymer is 1:2 to 2:1 (Column 9 lines 48-50). The catalyst used to react the diol and lactone may be stannous octoate, which is a synonym for tin-2-ethylhexanoate (see the attached chemical data sheet). The elements above meet the requirements of claims 1, 2, 3, 7, 13, 14, 15, 16, 20, 21, 22, 25, 26, 27, 28, 29, 30, 31 and 32. Since the composition requirements are met the properties of claims 4 and 18 are deemed inherently met by the composition. The A block may have 4-50 units therein (Column 4 line 45), as required by claims 5 and 6 and since the molar ratio and difunctionality of the coupling agent is met, the x macromeric units are found to be encompassed by the teachings of Cohn, as further required by claim 5. Since the lactone units always inherently comprise at least 80% of the polyester (i.e. 2 A units and at least 4 repeats therein equals 8 A units, plus 1 B unit and 1 C unit, 8/10=80%) claims 8 and 9 are met. A lactic acid "unit" would have a MW of 93, which meets the requirements of claims 10-12. The MW of the triblock spans 1,000-30,000, and as such when one chain extends with a 1:1 molar ratio one would expect a doubling of the MW, encompassing the range of claim 17.

---

[2] Fowler, column 1, lines 40-42
[3] Fowler, column 1, lines 49-55

Applicants note that, while Cohn describes polymers having some of the features of those presently claimed, none of them has a [B] block as recited in present claim 5, i.e., C_2-C_{14} alkanediyl groups. Rather, Cohn's [B] blocks are water-soluble or water-dispersible,[4] and are generally hydroxyl or amine terminated poly(oxyalkylene) blocks.[5] Cohn states his belief that the excellent anti-adhesion characteristics of his polymers are due to this choice of material for the [B] block.[6] In any case, Cohn fails to teach a [B] block containing C_2-C_{14} alkanediyl groups as presently claimed, and Applicants respectfully request that the rejection be withdrawn.

Claim Rejections - 35 USC § 103

12. Claim 36 is rejected under 35 U.S.C. 103(a) as being obvious over Spinu (US 202413) in view of Cohn (US 5711958). The Examiner argues as follows. Spinu includes elements as set forth above. Spinu discloses ABAN type degradable molded resins. Spinu does not disclose the use of bioactive agents with said resin. Cohn discloses methods for reducing post surgical adhesion formation. Cohn discloses using ABA triblocks comprising lactic acid A blocks and diol based B blocks (Column 3 lines 28-46), the same structure and monomer elements used by Spinu. Cohn also discloses linking the blocks together with acyl acids to form ABAN type degradable resins (Column 3 line 50). Cohn and Spinu thusly disclose very similar polymer compositions. Cohn discloses that such compositions are suitable for use in vivo to prevent surgical adhesion, and further discloses the incorporation of bioactive agents such as antibodies and the like (Column 16 lines 28-56) to further promote wound healing. The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In light of such it would have been obvious to one of ordinary skill in the art at the time of the invention to use the composition of Spinu in surgical healing, as taught by Cohn, since it is known in the art to be useful for such. Additionally, it would have been obvious to one of ordinary skill to include in Spinu the use of the bioactive agents taught by Cohn to enhance the healing of the surgical wounds to which the composition was applied to.

---

[4] Cohn, column 4, line 64
[5] Cohn, column 3, lines 42-44 and column 5, lines 8-11
[6] Cohn, column 5, lines 2-4

The rejection relies on Cohn to teach the use of bioactive agents, which are not taught by Spinu. Applicants note that claim 36 recites by reference the polymer composition of claim 5. As explained above, Spinu fails to teach all of the features of claim 5, and Cohn does not remedy this deficiency. Applicants respectfully request that the rejection be withdrawn.

13. Claims 15, 16, 17, 21, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler in view of Spinu. The Examiner argues as follows. Fowler includes elements as set forth above. Fowler discloses the ABA type polymers further reacted with diisocyanates to form higher molecular weight products (Column 9 lines 19-24). Fowler does not disclose diacyl halide chain extenders nor the end molecular weight of the chain extended polymer, as further required by the above claims. Spinu includes elements as set forth above. Spinu discloses very similar, if not the same, ABA type polymers further chain extended. The chain extension occurs with either diisocyanates or diacyl chlorides containing 8-20 carbon atoms (Column 5 lines 14-15). Spinu thusly teaches the functional equivalence of said chain extenders. It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Fowler the use of diacyl chlorides having 8-20 carbon atoms, as taught by Spinu, since they are recognized in the art as functional equivalents to diisocyanate chain extenders. Fowler does not disclose the end MW of the chain extended polymer, but Spinu discloses that an end MW of 10,000-250,000 is suitable for use in general elastomeric applications (Column 5 lines 31-32), the same end use disclosed by Fowler (Column 1 line 16). The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Therefore, in light of that and in light of the similar uses disclosed in Fowler and Spinu, it would have been obvious to one of ordinary skill to have an end MW of 10,000-250,000 to obtain an elastomeric polymer suitable for the intended use therein.

The rejection relies on Fowler to provide ABA type copolymers, and on Spinu to teach the use of diacyl chlorides as chain extenders that result in structure [D] of claim 5. Applicants note that the rejected claims recite by reference the polymer composition of claim 5. But because claim 5 recites [A] blocks that are not taught by Fowler, the modification of Fowler's polymers by using Spinu's chain extenders would not result in the claimed invention. Therefore, Applicants respectfully request that the rejection be withdrawn.

14. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler and McLain (US 5028667). The rejection states that Fowler discloses the use of 2-ethyhexanoic acid and the like as a catalyst (Column 8 line 41) but does not disclose the catalysts of claim 26. McLain discloses the living polymerization of lactone, the same polymerization occurring in Fowler. McLain disclose the use of oxides of yttrium and other rare earth metals (Column 5 lines 5-19). Said catalysts result in living polymerization, which is characterized by yielding narrow MW distributions, and allows the polymerized lactone to be stored under inert conditions and allows it to be further polymerized with another monomer. The Examiner indicates that it would have been obvious to one of ordinary skill in the art at the time of the invention to include the yttrium oxide catalysts of McLain in the composition of Fowler in order to obtain a narrow MW distribution in the resulting polymer composition.

The rejection relies on McLain to teach the specific recited catalyst. But McLain does not overcome the above-mentioned deficiencies of Fowler with respect to claim 5, whose features are included in claim 26, and so the combination of McLain and Fowler does not teach all of the claim features. Applicants therefore submit that the rejection has been overcome, and respectfully request that it be withdrawn.

15. Claim 36 is rejected under 35 U.S.C. 103(a) as being obvious over Fowler (US 2977385) in view of Cohn (US 5711958). The Examiner indicates that Fowler discloses ABAN type degradable molded resins, but does not disclose the use of bioactive agents with such resins. Cohn discloses methods for reducing post surgical adhesion formation. Cohn discloses using ABA triblocks comprising lactic acid-A blocks and diol-based B blocks (Column 3 lines 28-46), the same structure and monomer elements used by Fowler. Cohn also discloses linking the blocks together with acyl acids to form ABAN type degradable resins (Column 3 line 50). Cohn and Fowler thusly disclose very similar polymer compositions. Cohn discloses that such compositions are suitable for use in vivo to prevent surgical adhesion, and further discloses the incorporation of bioactive agents such as antibodies and the like (Column 16 lines 28-56) to further promote wound healing. The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In light of such it would have been obvious to one of ordinary skill in the art at the time of the invention to use the composition of Fowler in surgical healing, as taught by Cohn, since it is known in the art to be useful for such. Additionally, it would have been obvious to one of ordinary skill

to include in Fowler the use of the bioactive agents taught by Cohn to enhance the healing of the surgical wounds to which the composition was applied to.

Applicants note that Cohn does not overcome the above-mentioned deficiencies of Fowler with respect to claim 5 (whose features are included in claim 36), namely that Fowler does not teach the recited [A] blocks. In view of this, the combination of Fowler and Cohn would not result in the invention of claim 26, and Applicants respectfully request that the rejection be withdrawn.

16. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn in view of Fowler, for the following stated reasons. Cohn includes elements as set forth above. Cohn discloses the use of various lactides and caprolactones but does not disclose the use of substituted lactones. Fowler includes elements as set forth above. Fowler discloses similar ABA type lactide polymers further extended with diisocyanates. Fowler discloses the use of caprolactones and substituted caprolactones (Column 1 line 56- Column 2 line 5). Fowler thusly teaches the functional equivalence of said lactones. It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Cohn the use of the substituted caprolactones taught by Fowler since they are recognized in the art as functional equivalents of unsubstituted caprolactones.

The rejection relies upon Fowler to teach the use of substituted caprolactones to form feature [A] of the claimed polymer, and to use such a polymer in Cohn's invention to treat a patient to reduce surgical adhesions. But since the polymer recited in claim 5 (whose features are included in claim 19) cannot include caprolactones in feature [A], the use of Fowler's polymers in Cohn's invention would not result in the subject matter of claim 19. In view of this, Applicants respectfully request withdrawal of the rejection.

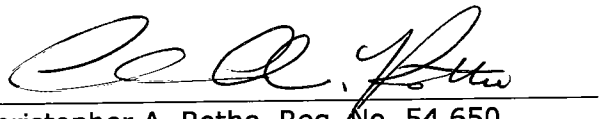
17. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn in view of Fowler, for the following reasons. Cohn includes elements as set forth above, and discloses various ethylene oxide/lactic acid ratios. However, Cohn does not disclose the molar ratio of the reactants. Fowler includes elements as set forth above. As set forth, Cohn and Fowler disclose similar chain extended lactone ABA polymers. Fowler discloses that one can control the average molecular weight of the product by preselecting the molar proportions, or ratio, of lactone to initiator (diol). For example, if one desires a MW 10 times larger than the initial MW the proportions of lactone to initiator are 10:1 (Column 10 lines 60-75). Fowler

teaches that higher MW polymers have greater elasticity (Column 11 line 20). Fowler thusly teaches the choice of molar ratio to be a result effective variable. The Examiner indicates that it would have been obvious to one of ordinary skill in the art at the time of the invention to manipulate the ethylene oxide/lactic acid ratios taught in Cohn, as taught by Fowler, in order to obtain the desired end molecular weight to obtain the desired elasticity and tensile strength properties.

The rejection relies on Fowler to teach that ethylene oxide/lactic acid ratio is a known result-effective variable, and that the diol/lactone ratios recited in claims 23 and 24 are obvious in view of Fowler's teachings. Applicants point out that ethylene oxide/lactic acid ratio is not relevant to claims 23 and 24, which incorporate the features of claim 5, because none of Cohn's polymers includes C_2-C_{14} alkanediyl groups in the [B] block as recited in present claim 5. Thus, Applicants request that the rejection be withdrawn.

Applicants submit that the application is now in condition for allowance, and respectfully request notification of same. Applicants invite the Examiner to contact Frank Tise, undersigned, if it appears that this may expedite examination.

Respectfully submitted,



Christopher A. Rothe, Reg. No. 54,650
Frank P. Tise, Reg. No. 50,379
Attorney and Agent for Applicants

CAR/FPT/ks

Attachments: Definition of "lactone" from the International Encyclopedia of Chemical Science

Dated: October 28, 2009

P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.
440786